NEW WAIVED TESTS

On March 6, 2003, the Food and Drug Administration (FDA) approved the **Genzyme OSOM Mono Test**, K972231/A006, for waived status for the analyte infectious mononucleosis antibodies (Mono). The waived test status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test system is waived under CLIA.

On March 17, 2003, the FDA approved the **Alatex Scientific Marijuana (THC) Home Drug Test**, K010921/A003, for waived status for the analyte cannabinoids (THC). The waived test status is applicable to the OTC test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test system is waived under CLIA.

On March 24, 2003, the FDA approved the **GI Supply, Div. Chek-Med Systems HP One**, K012411/A004, for waived status for the analyte Helicobacter pylori. The waived test status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test system is waived under CLIA.

On April 29, 2003, the FDA approved the **ADC CLIA Waived Marijuana (THC) Test**, K001567/A003, for waived status for the analyte cannabinoids (THC).

On April 29, 2003, the FDA approved the **ADC CLIA Waived Multiple Drug Test Card**, K001126/A004, for waived status for the analytes opiates, methamphetamines, cocaine metabolites, THC, and PCP. The waived test status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test system is waived under CLIA.

On April 30, 2003, the Food and Drug Administration (FDA) approved the **ADC CLIA Waived Marijuana (THC) and Cocaine Test**, K003708/A002, for waived status and for the analytes cannabinoids (THC) and cocaine metabolites. The waived test status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test system is waived under CLIA.

On May 1, 2003, the FDA approved the **Phamatech At Home Drug Test (Model 9150X)**, K030447, for waived status for the analytes methamphetamine/amphetamine, amphetamine, cocaine metabolites, opiates, and THC.

On May 8, 2003, the FDA approved the **Binax Now Flu A Test**, K021649/A4, for waived status for the analyte Influenza A. The waived test status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test system is waived under CLIA.

On May 8, 2003, the FDA approved the **Binax Now Flu B Test**, K021646/A4, for waived status for the analyte Influenza B. The waived test status is applicable to the test

system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test system is waived under CLIA.

On May 13, 2003, the FDA approved the **Beckman Coulter Icon Microalb**, K022538/A003, for waived status for the analyte albumin, urinary. The waived test status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test system is waived under CLIA.

On May 14, 2003, the FDA approved the **Hemocue Donor Hemoglobin Checker System**, BK030020, for waived status for the analyte Hgb, single analytes inst. w/self-cont.... The waived test status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test system is waived under CLIA.

On June 12, 2003, the Food and Drug Administration (FDA) approved the **ACON Strep A Twist Rapid Test**, K023766/A003, for waived status and for the analyte Streptococcus Group A. The waived test status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test system is waived under CLIA.

On June 24, 2003, the Food and Drug Administration (FDA) approved the **Applied Biotech, Inc., RU25 Plus FSH Menopause Test**, K023408/A001, for waived status and for the analyte follicle-stimulating hormone (FSH). The waived test status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test system is waived under CLIA.

On July 2, 2003, the Food and Drug Administration (FDA) approved the **Permaxim Rediscreen Strep A Rapid Test**, K0010582/A013, for waived status and for the analyte Streptococcus Group A. The waived test status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test system is waived under CLIA.

On July 8, 2003, FDA approved the **Sacks Medical Refuah Strep A Rapid Test**, K0010582/A012, for waived status and for the analyte Streptococcus Group A. The waived test status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test system is waived under CLIA.

POLICY FOR CONDUCTING ALTERNATE QUALITY ASSESSMENT SURVEYS (AQAS) UNDER CLIA

On June 16, 2003, the Survey and Certification Group (SCG) of the Centers for Medicare and Medicaid Services (CMS) sent a Survey and Certification memorandum to all Survey and Certification Regional Office Management (G-5) clarifying the May 20, 2003 correspondence concerning the change in policy for AQAS surveys.

Due to the publication of the Final Rule, CMS-2226-F, it will be necessary to conduct on-site visits to all eligible CLIA laboratories in FY 2004 and 2005. The AQAS will not be required for the next two years because we are doing on-site surveys.

LIST OF PROFICIENCY TESTING (PT) PROGRAMS APROVED FOR THE CALENDAR YEAR 2003 UNDER CLIA

On June 24, 2003, the Survey and Certification Group (SCG) of the Centers for Medicare and Medicaid Services (CMS) sent a Survey and Certification memorandum to all Survey and Certification Regional Office Management. This memorandum provided a list of PT programs that have been approved for certain specialties, subspecialties, analytes/tests for the calendar year 2003. These include:

American Association of Bioanalysts (AAB)
American Academy of Family Physicians (AAFP)
Accutest, Inc.
American Proficiency Institute (API)
California Thoracic Society (CTS)
The College of American Pathologists (CAP)
External Comparative Evaluation for Laboratories Excel
Idaho Bureau of Laboratories
Medical Laboratory Evaluation (MLE)
New Jersey Department of Health and Senior Services
Commonwealth of Pennsylvania
Puerto Rico Department of Health
Wisconsin State Laboratory of Hygiene
Maryland Department of Health and Mental Hygiene
New York State Department of Health

For a complete list of analytes, please access the CLIA website at:
www.cms.hhs.gov/clia/ptlist.pdf.

Not every survey module/package a PT provider offers is approved to meet certain CLIA PT enrollment and participation requirements (42 CFR Part 493, Subparts H/I). Laboratories are encouraged to contact the PT provider(s) directly to obtain explicit information pertaining to any particular company's PT services relative to CLIA.

Please note the Ohio Department of Health PT program was discontinued for the calendar year 2003.